Claims

1. A polycationic carbohydrate or a pharmaceutically acceptable derivative thereof, wherein the polycationic carbohydrate comprises a water-soluble alkylated chitosan, or a pharmaceutically acceptable salt or derivative thereof, a cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof, for use as an immunostimulant.

2. A polycationic carbohydrate according to claim 1 where the polycationic carbohydrate is a water-soluble alkylated chitosan derivative or a salt thereof, such as trimethyl chitosan chloride, N-carboxymethyl chitosan and polyethylene glycol chitosan.

3. A polycationic carbohydrate according to claim 2 in which the alkylated chitosan is a trimethylchitosan.

4. A pharmaceutical composition comprising a biologically active agent which is capable of generating a protective immune response in an animal, and a polycationic carbohydrate according to any one of claims 1 to 3.

5. A pharmaceutical composition according to claim 4 which further comprises a diluent or carrier.

6. A pharmaceutical composition according to claim 5 which comprises particles comprising

(i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;

(ii) a first material capable of forming particles; and

(iii) a polycationic carbohydrate according to any one of claims 1 to 3.

7. A pharmaceutical composition comprising particles, each particle comprising

(i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;

(ii) a first material capable of forming particles; and

(iii) one or more polycationic carbohydrates which have immunostimulant properties, wherein polycationic carbohydrate is distributed throughout the particle including at the surface.

8. A compositon according to claim 7 wherein the polycationic carbohydrate comprises an immunostimulant which is a chitin derivative, a cationic polypeptide, a cationic polyamino acid, a quaternary ammonium compound or a mixture thereof.

9. A composition according to claim 8 wherein the polycationic carbohydrate comprises a chitin derivative.

10. A composition according to claim 9 wherein the chitin derivative is chitosan, chitosan chloride, or chitosan glutamate or a polycationic carbohydrate according to claim 2 or claim 3.

11. A composition according to any one of claims 6 to 10 wherein the particle comprises microspheres, microparticles or liposomes.

12. A composition according to claim 11 wherein the particle comprises a microparticle.

13. A composition according to any one of claims 6 to 12 wherein the first material is a polymeric material which has a molecular weight of 100kDa or more.

14. A composition according to any one of claims 6 to 13 wherein the first material comprises poly-(L-lactide).

15. A composition according to any one of claims 6 to 14 wherein the ratio of the first material to the polycationic carbohydrate is from 99:1 to 9:1 w/w.

16. A composition according to any one of claims 6 to 15 wherein the biologically active agent is capable of generating a protective immune response against tetanus, diptheria, or *Yersinia pestis*.

17. A composition according to claim 16 wherein the biologically active agent comprises a combination of the V antigen of *Y. pestis* or an immunologically active fragment thereof, and the F1 antigen of *Y. pestis* or an immunologically active fragment thereof.

18. A composition according to any one of claims 6 to 17 which is adapted for intranasal application.

19. A composition according to any one of claims 6 to 17 which is adapted for parenteral administration.

20. A composition according to any one of claims 6 to 19 which further comprises a chemical compound selected from

A) a polyamino acid,
B) a vitamin or vitamin derivative,
C) cationic pluronics,
D) a clathrate,
E) a complexing agent,
F) cetrimides;
G) an S-layer protein; or
H) methyl-glucamine.

21. A composition according to claim 20 which further comprises a cationic pluronic.

22. A composition according to claim 21 which comprises nanospheres of a cationic pluronic which are surface modified with chitosan.

23. A method for producing a pharmaceutical composition, which method comprises encapsulating a biologically active agent in a first material, in the presence of a polycationic carbohydrate according to any one of claims 1 to 3.

24. A method for producing a pharmaceutical composition, which method comprises forming an emulsion of a biologically active agent and a first polymeric material, in the presence of an immunostimulant polycationic carbohydrate, and dropping the resultant emulsion into a secondary aqueous phase which also contains an immunostimulant polycationic carbohydrate.

25. A method according to claim 24 wherein the immunostimulant polycationic carbohydrate is a chitin derivative, cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof.

26. A method according to claim 25 wherein the polycationic carbohydrate is chitosan, chitosan chloride, chitosan glutamate or a water-soluble alkylated chitin derivative according to claim 2 or claim 3.

27. A method for producing a pharmaceutical composition which method comprises forming a microsphere, depositing a layer of polycationic carbohydrate thereon, and thereafter adsorbing a biologically active agent.

28. A method according to claim 27 wherein the immunostimulant polycationic carbohydrate is a chitin derivative, cationic polypeptide, cationic polyamino acid, a quaternary ammonium compound or a mixture thereof.

29. A method according to claim 28 wherein the polycationic carbohydrate is chitosan, chitosan chloride, chitosan glutamate or a water-soluble alkylated chitin derivative according to claim 2 or claim 3.

30. A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate according to any one of claims 1 to 3.

31. A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, in the form of a composition according to any one of claims 6 to 22.

32. A method according to claim 30 or claim 31 wherein the protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate is applied parenterally or to a mucosal surface.

33. A method according to claim 32 wherein the protective agent and the immunostimulant are applied to a mucosal surface.

34. A method according to claim 33 wherein said mucosal surface is an intranasal surface.

35. The use of a polycationic carbohydrate or a pharmaceutically acceptable derivative thereof according to any one of claims 1 to 3 as an immunostimulant, in the preparation of a vaccine for use in prophylactic or therapeutic treatment.

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(i) a biologically active agent which is able to produce an immune response in an animal to which it is administered;

(ii) a first material capable of forming particles; and

(iii) a polycationic carbohydrate according to claim 1.

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10. (Amended) A composition according to claim 9 wherein the chitin derivative is chitosan, chitosan chloride, or chitosan glutamate or a polycationic carbohydrate according to claim 2.

11. (Amended) A composition according to claim 6 wherein the particle comprises microspheres, microparticles or liposomes.

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13. (Amended) A composition according to claim 6 wherein the first material is a polymeric material which has a molecular weight of 100kDa or more.

14. (Amended) A composition according to claim 6 wherein the first material comprises poly-(L-lactide).

15. (Amended) A composition according to claim 6 wherein the ratio of the first material to the polycationic carbohydrate is from 99:1 to 9:1 w/w.

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16. (Amended) A composition according to claim 6 wherein the biologically active agent is capable of generating a protective immune response against tetanus, diptheria, or *Yersinia pestis*.

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18. (Amended) A composition according to claim 6 which is adapted for intranasal application.

19. (Amended) A composition according to claim 6 which is adapted for parenteral administration.

20. (Amended) A composition according to claim 6 which further comprises a chemical compound selected from

(A) a polyamino acid,

(B) a vitamin or vitamin derivative,

(C) cationic pluronics,

(D) a clathrate,

(E) a complexing agent,

(F) cetrimides,

(G) an S-layer protein, or

(H) methyl-glucamine.

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23. (Amended) A method for producing a pharmaceutical composition, which method comprises encapsulating a biologically active agent in a first material, in the presence of a polycationic carbohydrate according to claim 1.

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30. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate according to ~~claim~~ 1.

31. (Amended) A method of protecting an animal against a pathogen, said method comprising administering to said animal, a protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, in the form of a composition according to claim 6.

32. (Amended) A method according to claim 30 wherein the protective agent which is able to stimulate the animal's immune system to produce a response which is protective against said pathogen, and an immunostimulant comprising a polycationic carbohydrate is applied parenterally or to a mucosal surface.

35. (Amended) The use of a polycationic carbohydrate or a pharmaceutically acceptable derivative thereof according to claim 1 as an immunostimulant, in the preparation of a vaccine for use in prophylactic or therapeutic treatment.

Respectfully submitted,

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